EXHIBIT C

BethesdaTriHealthGood Samaritan

INFORMED CONSENT STATEMENT

Bethesda & Good Samaritan Sites

Protocol Title:	**Genetic and Environmental Risk Factors for Hemorrhagic Stroke**
Principal Investigator:	**Joseph P. Broderick, M.D. (513) 558-3760**
Co-investigators:	**Thomas Brott, M.D., Rashmi Kothari, M.D., Art Pancioli, M.D., Laura Sauerbeck, R.N., Edward Jauch, M.D.**
Study Sites:	**The University of Cincinnati Medical Center and 18 regional hospitals (including Bethesda Oak Hospital, Good Samaritan Hospital, and Bethesda North Hospital). Patients will also be interviewed at home, nursing homes, or rehabilitation facilities.**

INTRODUCTION

It is important that I understand the following information before I agree to be a part of this study. I will understand the goals and steps involved. I will be warned of possible dangers or things that may make me uncomfortable. I will also be warned of any other things that I may need to know about before starting the study. The information will also give me other options I have if I choose not to be in the study. I may stop being in the study any time. I am not being promised certain results. I am volunteering to be in this study. No one is forcing me. If I do not want to be in the study I will still get the standard care available to patients not in the study.

OBJECTIVES OF THE STUDY

I, Pam Silvey, agree to participate in a medical research study, the goal of which is to determine the significant environmental and genetic risk factors and the causes of intracerebral hemorrhage and subarachnoid hemorrhage. The genes that will be tested in this study are the genes for Apo-E (a gene that determines the level of blood protein that is also found in the brain), alpha-1-antitrypsin (a gene which may be related to the formation of aneurysms of blood vessels in the brain), and the amiloride-sensitive sodium channel (a gene which controls the level of salt in cells). Other stroke-related genes may be discovered in the future. If so, I may be contacted to use my tissue samples to evaluate the presence of any of the newly discovered genes.

IRB *Approved* ICS NOV 10 1997

DEFENDANT'S EXHIBIT

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This study is under the direction of LAURA SAUERBECK and the medical supervision of Dr. Joseph P. Broderick, M.D. Other professional persons who work with them as study staff may assist or act for them.

I will be one of approximately 720 subjects to participate in this trial.

FINANCIAL COSTS TO THE SUBJECT:

I understand that being in this research program will not cost me anything beyond that of the standard treatment. There will be no additional personal expense. If I have questions about my medical bill relative to research participation, I may contact Joseph P. Broderick, M.D.

DURATION:

My participation in this study will last initially for approximately one hour (including a 45 minute interview, and 15 minutes for blood pressure determination and obtaining a buccal cell sample). In addition I will be contacted by telephone at three months and six months after onse for a phone interview concerning my present state of health and independence (each phone interview will last approximately 30 minutes). If I have a family history of ruptured cerebral aneurysm, I may also be contacted at a future date to participate in genetic linkage studies.

PROCEDURES:

I am under the care of a physician. I understand that my physician, Dr. VAN LOVEREN has given permission for me to take part in this study. (If the patient is not under the care of a physician, simply enter N/A in the blank for the physician's name.)

I have been told that during the course of this study, the following will occur:

I will be asked a series of questions about my medical history and medication I may have rece taken. This interview should only take about 30-45 minutes.

I will have my blood pressure taken 3 times one minute apart.

A sample of my buccal cells (cells lining the cheek inside the mouth) will be obtained. This involves rinsing my mouth gently with water prior to having the sample obtained. Then a che brush will be inserted in my mouth and twirled firmly against my inner right cheek for 30 seconds. A second set of buccal cells will be obtained from my left inner cheek with the sam method. This procedure will be repeated an additional time on each cheek (a total of four buc brushes).

At three months and six months I will be contacted by telephone and asked questions c my present state of health and independence (each telephone interview will last approx. minutes).

RISK/DISCOMFORTS:

Possible discomforts include having my arm "squeezed" during the blood pressure read possible irritation from the cheek brush.

There may be risks and discomforts which are not yet known.

CONFIDENTIALITY:

I understand that information regarding genetic testing will not be released to any indiv including myself or my family members.

PREGNANCY:

If I am a woman and I am or should become pregnant, there is no risk to me or my fetus participation in this study.

BENEFITS:

I have been told that I will receive no direct benefit from my participation in this study, participation may help health care practitioners better understand the potential environr genetic risk factors associated with intracerebral and subarachnoid hemorrhage.

AVAILABILITY OF INFORMATION:

Any questions that I may have concerning any aspect of this investigation will be answ Dr. Joseph P. Broderick, M.D., Principal Investigator or an associate at (513) 558-376(

Records involving participation in this investigation will be held confidential. Since th clinical investigation, my records will be subject to sponsor, TriHealth Institutional Re Board and possibly Food & Drug Administration review or other governmental agencie

The TriHealth Network: I understand that Bethesda Hospital, Inc. (including Bethesda Hospital and Bethesda North Hospital) and The Good Samaritan Hospital of Cincinnat have become affiliated in a network through a new company known as TriHealth, Inc. TriHealth Network also includes other companies and health care providers. I understı my care during this admission/treatment may involve one or all of these companies/pro that everyone who participates in my care needs to have access to all of my TriHealth r

I agree that all medical records and other information concerning me which has been acqui the past or is acquired during this admission/treatment by any health care provider in the TriHealth Network may be released or disclosed as may be needed to care for me to any ot healthcare provider in the TriHealth Network.

COMPENSATION IN CASE OF INJURY:

There is a chance that I might be injured during any study in medicine or behavior. The st may or may not be the cause. It has been explained to me whether I can be treated and/or compensated. TriHealth makes all decisions case by case. This is the policy of TriHealth. understand I will not get payment for being injured. If I think the study has injured me I w Joseph P. Broderick, M.D., at (513) 558-5748. If I have any more questions about this, or being in the study, I may call Dr. V. Franklin Colón. His phone number is (513) 872-1650 is the Chair of the Institutional Review Board for TriHealth. This Board reviews research projects. It makes sure that the rights and welfare of patients in studies are protected.

RIGHT TO REFUSE OR WITHDRAW:

I understand that being in this study is voluntary. I am free to withdraw at any time. There not be any prejudice to my continued medical care if I wish to withdraw. The standard tre for my condition will still be available to me. I understand that I have the right to ask ques at any time. All questions will be answered to the best of my doctor's ability. During the s there may be significant new findings. This may relate to my willingness to continue. Thi information will be provided to me.

I have read the description of this investigation. I have been informed of the probable consequences of my withdrawal from the study. I freely give my consent to participate.

PARTICIPATION IN ANOTHER STUDY:

Is the subject participating in another study? If yes, please provide the Principal Investiga name and title of the study.

TITLE OF STUDY:

_____

_____

INSTITUTIONAL STUDY NUMBER: _____

SPONSOR STUDY NUMBER: _____

WITNESSING AND SIGNATURES:

I HAVE RECEIVED A COPY OF THIS INFORMED CONSENT STATEMENT.

1. Pam Silvey — Subject (PRINTED NAME)
Pam Silvey 2- — Subject (SIGNATURE)

2. Diana Oberschmidt — Witness (PRINTED NAME)
Diana Oberschmidt 2-1 — Witness (SIGNATURE)

3. Joseph Broderick — Approved Investigator (PRINTED NAME)
(Must Be An IRB APPROVED Investigator)
Approved Investigator (SIGNATURE) -2

Ethnic Origin of Subject: ☐ African-American ☐ Asian ☒ Caucasian ☐ Hispanic ☐ Native American ☐ Other _____

In 1994 the Office for Protection from Research Risk (OPRR), National Institutes of Health (NIH) and the Food & Administration (FDA) established a requirement that information regarding gender and minority status be obtaine

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The following is required if subject is unable to sign or under the age of 18 years old:

Relationship to Subject (i.e. mother/father/guardian)

Family Member or Guardian (SIGNATURE)

The Informed Consent Statement should be signed by the subject (or his/her legal representative minor or unable to sign personally), the investigator, and one witness who attests that the Conse was presented and those questions asked by the subject in the presence of the witness were answ

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Once an Informed Consent Statement is completed, a copy is required to be given to the following partic

1) original - patient's hospital record
2) copy to the patient
3) copy kept by the investigator
4) copy to the IRB Office (mail or fax 872-1549) within five (5) working days

FDA requires notation of patient's informed consent into this study be documented within the phy patient's hospital (if applicable) and office charts (located in the investigator's o

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